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| EXAMINER |
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PATEL, SHEFALI DILIP

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| ART UNIT | PAPER NUMBER |
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3767

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06/06/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/565,734 | Applicant(s) RODD, AARON | |
| | Examiner SHEFALI D. PATEL | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2006 and 27 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>01/24/2006, 12/19/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file: Provisional specification of AU 2003903990, filed July 31, 2003.

Claim Objections

2. Claims 1, 2, and 18 are objected to because of the following informalities:

In regards to claim 1, there appears to be an error with the limitation “a needle holder...”. The limitation states that “a first position where the release means locks the needle holder to the outer tubular member, and a second position where the release means is unlocked from the **inner tubular member**”. In Applicant’s Figures, the first position is shown in Figure 8A, in which the release means [28] is locked to the outer tubular member [11], and the second position is shown in Figure 9A, in which the release means [28] is unlocked from the outer tubular member [11]. It is not shown that the release means is unlocked from the **inner tubular member** since the release means was not previously locked to the inner tubular member. The discrepancy between the Figures and the claim appears to be an inadvertent error and the claim should be corrected if such be the case.

In regards to claim 2, to avoid confusion with the “outer tubular member” the usages of “tubular member” should be corrected as “inner tubular member”.

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In regards to claim 18, the term “**upper** tubular member” has not been used before; however, it is the Examiner's understanding that the term should be corrected as “**inner** tubular member” to be consistent with prior claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 18, the term "release means" is unclear as it has not been identified as the "release means of the end member" or the "release means of the needle holder", which have both been defined in claim 1, which precedes claim 18.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the

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international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 2, 5-16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Barker et al (US 6,569,115).

In regards to claims 1, 2, 15, 16, and 18, Barker et al teaches a device (Figures 4-7) comprising:

- a. an outer tubular member (housing [20])
- b. an inner tubular member (vial [60]) (column 4, lines 27-34)
- c. an end member/needle holding piston assembly (piston/plug [64]) having sealing means (column 4, lines 34-38)
- d. release means (recesses [67a][67b] and flared head [68]) on the end member/needle holding piston assembly [64] and which is movable between a first position where the release means [68] locks the end member [64] to the inner tubular member [60] (Figures 4-5), and a second position where the release means [68] is unlocked from the inner tubular member [60] and allows the end member [64] to retract through the inner tubular member [60] (Figures 6-7) (column 5, lines 28-32)
- e. a needle holder (needle retainer [40]), release means (barb [32] and locking tabs [44]) on the needle holder and which is moveable between a first position where the release means locks the needle holder to the outer tubular member [20] (Figures 4-5), and a second position where the release means is unlocked from the **outer** tubular member (Figures 6-7)

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From Applicant's specification and figures, the sealing means is a seal [31] (Page 14), the release means on the end member are fingers [32] (Page 15), and the release means on the needle holder are fingers [27] (Page 14).

In regards to claims 5 and 6, Barker et al teaches gripping means (locking apertures [26]) on the outer tubular member [20] which lock the needle holder [40] to the outer tubular member (column 4, lines 16-20). *From Applicant's specification and figures, the gripping means is a recess/groove (Page 5).*

In regards to claims 7 and 8, Barker et al teaches that the end member [64] comprises a rear portion and a front portion, wherein the rear portion contains the sealing means to enable the end member to sealingly and slidably engage the inner wall of the inner tubular member [60] (column 4, lines 34-38) and the front portion contains the release means [68].

In regards to claim 9, Barker et al is silent about whether the release means [68] is resilient (column 4, lines 33-34); however, since the release means [68] is an element of the elastomeric end member [64] (column 4, lines 44-45), it naturally follows that the release means is also elastomeric/resilient. Also, Barker et al teaches that the release means [68] is at least one finger member, as can be seen in Figures 4-7.

In regards to claim 10, Barker et al teaches that the at least one finger member [68], when in the first position (Figures 4-5), locks against the open proximal wall of the inner tubular member [60].

In regards to claim 11, Barker et al teaches that the at least one finger member [68] has an arrowhead configuration, since an arrowhead is defined as a "pointed head" and the at least one finger member [68] is pointed (Figures 4-7).

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In regards to claim 12, Barker et al teaches that the needle holder [40] has a central body portion with a passageway to accommodate a puncture needle [50] (Figures 4-7) and the release means [32][44] being integral with the central body portion (Figures 4-7).

In regards to claim 13, Barker et al teaches that the release means comprises at least one finger [32] to enable the finger member to engage with release means [67a][67b] on the end member [68] (Figures 10-11). The release means also comprises another finger member [44].

In regards to claim 14, Barker et al teaches that the finger member [44] engages with a recess [26] in the outer tubular member [20] to releasably lock the needle holder [40] to the outer tubular member [20] (Figures 4-5).

7. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Shaw (US 6,090,077).

In regards to claim 17, Shaw teaches a device (Figures 1-3) comprising:

- a. an outer tubular member (outer body [12])
- b. an inner tubular member (plunger [32])
- c. needle retraction means (retraction mechanism [20]) to enable the puncture needle [28] to be retracted into the inner tubular member [32] upon forward movement of the inner tubular member relative to the outer tubular member [12] (Figure 3) (column 6, lines 63-66)

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- d. limit means (outer periphery [60] with opening [58]) to limit the travel of the inner tubular member [32] relative to the outer tubular member [12], the limit means being adjacent a distal end of the device (Figure 3) (column 7, lines 23-26)

From Applicant's specification and figures, the limit means are a rib [24] and adjacent internal beads [25] forming a groove to fit the rib [24], and the needle retraction means is a retractable needle assembly [42] comprising outer and inner tubular members (Page 17).

- 8. Claims 1, 2, 4-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Shue et al (US 6,921,386).

In regards to claims 1, 2, 15, 16, and 18, Shue et al teaches a catheter introducer (Figures 3-8 and 11) comprising:

- a. an outer tubular member (barrel [2])
- b. an inner tubular member (plunger [4])
- c. an end member/needle holding piston assembly (seal member [43]) having sealing means
- d. release means (sealing portion [434] and segment [433]) on the end member/needle holding piston assembly [43] and which is movable between a first position where the release means [434] locks the end member [43] to the inner tubular member [4] (Figures 4-6), and a second position where the release means [434] is unlocked from the inner tubular member [4] and allows the end member [43] to retract through the inner tubular member [4] (Figures 8 and 11) (column 7, lines 46-49 and 60-63)

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- e. a needle holder (needle seat [31]), release means (segments [314][315]) on the needle holder and which is moveable between a first position where the release means locks the needle holder to the outer tubular member [2] (Figures 3-7), and a second position where the release means is unlocked from the **outer** tubular member (Figures 8 and 11) (column 5, lines 5-10)

From Applicant's specification and figures, the sealing means is a seal [31] (Page 14), the release means on the end member are fingers [32] (Page 15), and the release means on the needle holder are fingers [27] (Page 14).

In regards to claim 4, Shue et al teaches that the proximal end of the outer tubular member [2] is restricted in diameter with respect to the remainder of the outer tubular portion since the outer tubular member has stepped portions: larger-diameter segment [212], shoulder portion [213], and smaller diameter segment [211] (Figure 3).

In regards to claims 5 and 6, Shue et al teaches locking means (segment [226] in the form of a groove) on the outer tubular member [2] which lock the needle holder [31] to the outer tubular member (column 5, lines 5-10). *From Applicant's specification and figures, the gripping means is a recess/groove (Page 5).*

In regards to claims 7 and 8, Shue et al teaches that the end member [43] comprises a rear portion and a front portion, wherein the rear portion contains sealing means to enable the end member to sealingly and slidably engage the inner wall of the inner tubular member [4], as the rear portion is a component of the end member (seal member [43]), and the front portion contains the release means [434] (Figure 3).

In regards to claim 9, Shue et al is silent about whether the release means [434] is resilient; however, since the release means [434] is an element of the elastomeric end member [43] (column 5, lines 46-48), it naturally follows that the release means is also elastomeric/resilient. Also, Barker et al teaches that the release means [68] is at least one finger member, as can be seen in Figure 3.

In regards to claim 10, Shue et al teaches that the at least one finger member [434], when in the first position (Figures 4-6), locks against the open proximal wall of the inner tubular member [4].

In regards to claim 11, Shue et al teaches that the at least one finger member [434] has an arrowhead configuration, since an arrowhead is defined as a “pointed head” and the at least one finger member [434] is pointed (Figures 3-7).

In regards to claim 12, Shue et al teaches that the needle holder [31] has a central body portion with a passageway to accommodate a puncture needle (needle cannula [32]) and the release means [314][315] being integral with the central body portion (Figure 3).

In regards to claim 13, Shue et al teaches that the release means comprises at least one finger [315] to enable the finger member to engage with release means [433] on the end member [43] (Figures 5-8)(column 6, lines 18-20). The release means also comprises another finger member [314].

In regards to claim 14, Shue et al teaches that the finger member [314] engages with a groove [226] in the outer tubular member [2] to releasably lock the needle holder [3] to the outer tubular member [20] (Figure 7)(column 5, lines 5-10).

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In regards to claim 17, Shue et al teaches a catheter introducer (Figures 3-8 and 11) comprising:

- a. an outer tubular member [2]
- b. an inner tubular member [4]
- c. needle retraction means to enable the puncture needle [32] to be retracted into the inner tubular member [4] upon forward movement of the inner tubular member relative to the outer tubular member [2] (Figure 4 to Figure 5)
- d. limit means (rib segment [225] and rib segment [425]) to limit the travel of the inner tubular member [4] relative to the outer tubular member [2], the limit means being adjacent a distal end of the device (Figures 3-8) (column 4, lines 52-55)(column 5, lines 41-42)(column 6, lines 9-11)

From Applicant's specification and figures, the limit means are a rib [24] and adjacent internal beads [25] forming a groove to fit the rib [24], and the needle retraction means is a retractable needle assembly [42] comprising outer and inner tubular members (Page 17).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al, as applied to claim 2 above, and further in view of Shaw.

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In regards to claim 3, Barker et al does not teach captive means at the distal end of the outer tubular member and the distal end of the inner tubular member to limit travel of the inner tubular member within the outer tubular member. Shaw teaches a syringe (Figures 1-3) in which an outer tubular member (outer body [12]) has an opening [58] which limits the travel of an inner tubular member (plunger [32]) when the outer periphery [60] of the inner tubular member [32] engages with the opening [58] (column 7, lines 23-26). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the outer tubular member and the inner tubular member of Barker et al to have captive means, as taught by Shaw, as the captive means will prevent tampering of the retracted needle/needle holder (column 9, lines 59-66) since the inner tubular member will remain in engagement with the outer tubular member, through the captive means, to keep the open distal end of the outer tubular member closed by the placement of the inner tubular member. *From Applicant's specification and figures, the captive means are a rib [24] and adjacent internal beads [25] forming a groove to fit the rib [24].*

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shue et al.

In regards to claim 3, Shue et al teaches captive means on the outer tubular member [2] and the inner tubular member [4], wherein the captive means function to restrain movement of the inner tubular member [4] relative to the outer tubular member [2]; the captive means comprise a rib segment [225] on the outer tubular member [2] and a projection (rib segment [425]) on the inner tubular member [4] (column 4, lines 52-55)(column 5, lines 41-42)(column 6, lines 9-11). However, claim 3 requires that the

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captive portion of the outer tubular member is a passageway and not a rib, as taught by Shue et al. But it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the captive portion of the outer tubular member of Shue et al to be a passageway instead of a rib, since it was known in the art that a projection/passageway engagement is stronger and will function more efficiently to restrain the movement of the inner tubular member relative to the outer tubular member than a projection/projection (rib/rib) engagement. *From Applicant's specification and figures, the captive means are a rib [24] and adjacent internal beads [25] forming a groove to fit the rib [24].*

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Shaw et al (US 2003/0083621).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/

Examiner, Art Unit 3767

06/02/2008

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767